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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,071	02/06/2004	Maria Antonia Garcia-Olmedo Dominguez	2809-1-001	4812

7590 07/28/2005

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,071	DOMINGUEZ, MARIA ANTONIA GARCIA-OLMEDO	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending in this application.

Information Disclosure Statement

The information disclosure statement filed 7/26/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because an English equivalent or an English abstract of the non-patent literature was not submitted. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1). Note that the US patent and foreign patents have been considered.

Claim Objections

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 16 is directed an injectable foam both already prepared and as an extemporaneous preparation, in accordance with claim 1, characterized in that it is formed with inert foaming agents and any gas." However, "foam for injectables formed with inert foaming agents and any gas" is a limitation of the parent claim 1 and thus claim 16 does not further limit claim 1.

Claims 1-16 are objected to because of the following informalities: Applicant has capitalized certain terms in the claims and this is improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to "a pharmaceutical form of injectable foam, both already prepared and as an extemporaneous preparation, characterized to include any medicinal substance or drug other than sclerosing agents as well as foam for injectables formed with inert foaming agents and any gas." Firstly, the phrase "both already prepared and as an extemporaneous preparation" is vague and indefinite since it is unclear what the intended limitation of this phrase is. Furthermore, it is unclear what "both" refers to. Secondly, it is unclear what the intended limitation of the phrase "characterized to include any medicinal substance or drug other than sclerosing agents" is. There are two possible interpretations that "other than" implies: 1) the claim is attempting to exclude sclerosing agents or 2) the claims requires another medical substance in addition to the sclerosing agent. The examiner suggests restructuring the claim. It should be noted that any amendment made to clarify the claims must be supported by the instant specification. For prosecution purposes, the examiner will apply prior art based on both interpretations.

Regarding claim 6, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0656203.

EP discloses an injectable microfoam comprising a mixture of oxygen and carbon dioxide, a sclerosing agent, and a foaming agent. See example 1.

It should be noted that the instant claim is broadly directed to "any medical substance" and thus EP's oxygen reads on the "medical substance" since oxygen is utilized as a therapeutic agent. EP's carbon dioxide on the instant "gas". Further, the 112 indefinite rejection should be noted with regard to the sclerosing agent.

Claims 1-5, 7, and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al (5,733,572).

Unger et al disclose gas filled microspheres that include drugs or cosmetics, for topical or subcutaneous delivery. See abstract. Subcutaneous administration of active ingredients means administration that is below the surface of the patient's tissue, especially skin, by injection. Unger discloses that while subcutaneous administration ordinarily and predominantly

is the administration by injection underneath the skin of a patient, in the terms of the invention, the term subcutaneous is not limited and includes administration by injection below any and all tissue surfaces of a patient, whether external or internal (underneath the surface of a patient's eye or heart outer membrane). See column 2, lines 6-21.

Unger discloses that the gas is any biocompatible gas that will not result in any degree of unacceptable toxicity, including allergenic responses and disease states, and preferably are the gas is inert. See column 9, lines 55-65. The composition includes agents that influence the smoothness, volume and uniformity of the preparation. These agents are sodium lauryl sulfate and foaming agents. See column28, lines 4-6 and claim 8. It should be noted that surfactants also read on "foaming agents".

Unger discloses that the gas filled microspheres take the form of a foam that provide a creamy texture and skin penetration-enhancing qualities for topical or subcutaneous delivery of active agents. See column 5, lines 57-63 and column 6, lines 63-66. Unger discloses that the microspheres and foams of the invention with respect to delivery of active agent provide significant advantages. See column 3, lines 25-30 and column 50, lines 10-20.

Therapeutic agents disclosed include instant antibiotics, cardiovascular drugs, vasodilators (nitroglycerin), antifungals, antibacterials, chemotherapeutic, corticosteroids (hydrocortisone), anesthetics, prostaglandin, antiviral agents, hormones, and anti-inflammatories. See claim 1 and column 21-27. Note that chemotherapeutic drugs also read on cytostatic drugs.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Schutt et al (5,372,195).

Schutt discloses mixed gas microbubbles comprising a first gas, a second gas, contrast agent, and any foaming agent (surfactant) that provides for the formation of the microbubbles, in an liquid medium. See abstract and column 12, lines 1-4. The composition is capable of being injected into the body. See examples.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (5,733,572) in view of Rowe (6,468,964).

Unger et al disclose gas filled microspheres that include drugs or cosmetics, for topical or subcutaneous delivery. Unger discloses various therapeutic agents that are suitable including antibiotics. See claim 1.

However, Unger does not teach the instant sulphonamide class of antibiotics.

Rowe teaches controlling acidic gut syndrome with antibiotics such as sulphonamide antibiotics. See claim 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Unger et al and Rowe and utilize the instant class of antibiotics. One would have been motivated to do so since Rowe teaches sulphonamide antibiotics are used to control acidic gut syndrome. The selection of a particular drug depends on the disease or symptoms to be treated and thus this drug selection process is considered prima facie obvious. Moreover, a skilled artisan would have expected similar results since Unger teaches a variety of drugs that are suitable for the invention including antibiotics.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (5,733,572) in view of Rowe (6,468,964).

Unger et al disclose gas filled microspheres that include drugs or cosmetics, for topical or subcutaneous delivery. Unger discloses various therapeutic agents that are suitable including antibiotics. See claim 1.

However, Unger does not teach the instant sulphonamide class of antibiotics.

Fitzgerald teaches methods and compositions comprising bismuth and antimicrobial for treating gastrointestinal disorders. Fitzgerald teaches trimethoprim as a suitable antibiotic. See 4, line 63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Unger et al and Fitzgerald and utilize the instant class of antibiotics. One would have been motivated to do so since Fitzgerald teaches trimethoprim antibiotics are used to treat gastrointestinal diseases. The selection of a particular drug depends on the disease or symptoms to be treated and thus this drug selection process is considered prima

facie obvious. Moreover, a skilled artisan would have expected similar results since Unger teaches a variety of drugs that are suitable for the invention including antibiotics.

Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
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SSG

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